PERFORMANCE VERIFICATION OF QUALITATIVE MYCOTOXIN AND BIOTECH RAPID TEST KITS

1. PURPOSE

This directive describes the Grain Inspection, Packers and Stockyards Administration (GIPSA) procedures for verifying the performance of qualitative mycotoxin and biotechnology rapid test kits.

This directive does not establish approval to use the test(s) for official purposes.

2. REPLACEMENT HIGHLIGHTS

This directive is revised to include performance verification testing of qualitative mycotoxin test kits in GIPSA's verification testing program, and to change the testing authority from the Agricultural Marketing Act of 1946 to the United States Grain Standards Act (USGSA).

This directive supersedes FGIS Directive 9181.2, dated 2-7-02.

3. BACKGROUND

To meet the grain industry's demand for accurate and reliable qualitative mycotoxin and biotechnology event testing, the test kit manufacturers have asked GIPSA to provide a program to verify test kit performance claims, and subsequently issue a Certificate of Performance for test kits meeting these claims. In response to this request, GIPSA has established a program for verifying the performance of qualitative rapid tests to detect the presence of mycotoxins and/or biotechnology events present in grains and oilseeds.

4. PROGRAM DEFINITIONS

Mycotoxins: Toxic substances produced by fungi (molds) growing on grain, feed, or food. These toxins may be hazardous to humans and/or animals.

Biotechnology-Derived Grains and Oilseeds: Grains and oilseeds that have been altered using recombinant DNA technology (genetic engineering) to modify agronomic and/or quality characteristics.

Non-biotechnology Grains and Oilseeds: Grains and oilseeds that have not been modified through modern biotechnology.

Microtiter Well Enzyme-Linked Immunosorbent Assay (ELISA) Technology: Tests designed to detect specific mycotoxins in grains and oilseeds or specific proteins produced in biotechnology-derived grains and oilseeds, as applicable. These tests provide results using antibodies incorporated into microtiter wells and enzymatic colorimetric reagents for detection.

Lateral Flow Strip Technology: Tests designed to detect mycotoxins in grains and oilseeds or specific proteins produced in biotechnology derived grains and oilseeds, as applicable. These tests generally provide results using antibodies and color reagents incorporated into a lateral flow strip.

Control Samples: Samples of grain or oilseeds that do not contain mycotoxins or biotechnology-derived grain and oilseeds, as applicable.

Fortified Samples: Samples of grain or oilseeds with a predetermined concentration of mycotoxin(s) or biotechnology-derived grain through the addition of (a) the corresponding fungus-infected grain or oilseeds or (b) the corresponding biotechnology-derived grain or oilseeds, as applicable.

5. RAPID TEST PERFORMANCE EVALUATION PROGRAM

The Rapid Test Performance Evaluation Program established by GIPSA is a basic four step process where:

- The rapid test manufacturer submits a data package supporting their claims.
- The GIPSA staff reviews the data submitted by the manufacturer.
- If the data package is complete and the claims of the rapid test are supported by the data, GIPSA conducts an in-house performance verification of the rapid test.
- If the manufacturer's claims are verified by the GIPSA in-house performance testing, a Certificate of Performance is issued to the manufacturer for the rapid test.

6. MANUFACTURER INFORMATION

a. Detection Level.

The manufacturer is required to submit data that supports the claims of the rapid test.

(1) Mycotoxin Test Kits.

The test must detect the presence of the mycotoxin(s) in samples of the corresponding fungus-infected grain /oilseed at the Limit of Detection claimed by the manufacturer.

(2) Biotech Test Kits.

The test must detect the presence of the biotechnology-derived grain/oilseed at the Limit of Detection claimed by the manufacturer.

Since these tests are generally designed to detect the presence of a protein, and protein expression levels can vary significantly, the manufacturer should establish the Limit of Detection consistent with the lowest expression level.

b. General Information.

To submit a rapid test to GIPSA for performance verification, the manufacturer must submit the following information to the Test Kit Program Manager.

- Manufacturer name and address.
- Manufacturer contact person.
- Telephone number.
- Fax number.
- E-mail address.
- Test Format: Lateral Flow Strip, Microtiter Well Assay, or Other (specify).
- Matrix: Corn, Soybeans, Other (specify).
- Mycotoxin(s) Detected. (applicable to mycotoxin test kits only)

- Trait(s)/Events(s) Detected. (applicable to biotech test kits only)
- Limit of Detection.
- Rapid test user instructions.

Send this information along with the testing data as specified in section 7 below to:

Test Kit Program Manager
USDA, GIPSA, TSD
10383 North Ambassador Drive
Kansas City, MO 64153-1394

7. MANUFACTURER DATA SUBMISSION

To support claims with respect to the particular rapid test, the manufacturer is required to submit the following data to GIPSA:

a. Control Samples.

One hundred twenty (120) independent analyses, using three different test lots. All test results must be negative for the mycotoxin/biotechnology event of interest.

b. Fortified Samples.

One hundred twenty (120) independent analyses, using three different test lots, at the claimed Limit of Detection. All test results must be positive for the mycotoxin/biotechnology event of interest.

c. Performance of Rapid Test at 18^{o} C and 30^{o} C.

Data must be provided demonstrating acceptable performance of the test at 18^{o} C and 30^{o} C. Samples, equipment and testing materials must be equilibrated at the testing temperature for one hour prior to conducting the analyses.

Note: This requirement is waived for Lateral Flow Strip tests.

(1) Control sample analyses at 18^{o} C.

Fifteen (15) independent analyses. All test results must be negative for the mycotoxin/biotechnology event of interest.

(2) Fortified sample analyses at 18° C.

Fifteen (15) independent analyses. All test results must be positive for the mycotoxin/biotechnology event of interest.

(3) Control sample analyses at 30° C.

Fifteen (15) independent analyses. All test results must be negative for the mycotoxin/biotechnology event of interest.

(4) Fortified sample analyses at 30° C.

Fifteen (15) independent analyses. All test results must be positive for the mycotoxin/biotechnology event of interest.

d. Cross Reaction with other Biotechnology Events. (Biotech Test Kits Only)

Data from five (5) independent tests of all other biotechnology events in commercial production in the U.S. demonstrating the test does not detect proteins produced by other biotechnology events. All tests must be negative.

8. GIPSA REVIEW AND PERFORMANCE VERIFICATION

Upon receipt of the data submission from the manufacturer, GIPSA will:

- Review the data submission for completeness and compliance with GIPSA performance standards as stated above.

- Advise the manufacturer that the test met or did not meet the performance specifications.

If the test did not meet GIPSA performance specifications, the manufacturer will be given an opportunity to correct any deficiencies and will be allowed to submit the data a second time. If deficiencies cannot be corrected immediately, the manufacturer must wait a minimum of six months before resubmitting data for a GIPSA evaluation.

If the test does meet performance specifications, GIPSA will contact the manufacturer and identify a mutually agreeable date for the manufacturer to train GIPSA staff in the operation of the test. While training is advisable, at the manufacturer's discretion, training of GIPSA staff can be waived.

The evaluation will consist of a GIPSA analysis of control and fortified samples as specified below:

(1) Control Samples.

Thirty (30) independent analyses will be conducted, using three different test lots. All test results must be negative for the mycotoxin/biotechnology event of interest.

(2) Fortified Samples.

Thirty (30) independent analyses will be conducted, using three different test lots, at the claimed Limit of Detection. All test results must be positive for the mycotoxin/biotechnology event of interest.

9. EVALUATION SERVICE FEE

Section 800.71(a) of the regulations in the USGSA provide for a miscellaneous service fee for specialized services, such as performance evaluations. GIPSA will assess a service fee to test kit manufacturers for each performance evaluation conducted by GIPSA personnel. The fees will cover, as nearly as practicable, GIPSA's costs for the service, including related administrative and supervisory costs. The fee is applicable to all kits submitted to GIPSA for evaluation, regardless of whether the kits meet or do not meet GIPSA performance standards.

10. CERTIFICATE OF PERFORMANCE

Rapid tests that successfully meet GIPSA performance standards will be awarded a Certificate of Performance. The Certificate of Performance automatically expires three (3) years from the date of issue. The manufacturer will be required to provide GIPSA performance data prior to the expiration date to have the Certificate of Performance renewed for an additional three years.

GIPSA reserves the right to rescind the Certificate of Performance if:

- The manufacturer fails to notify GIPSA of changes or alterations to the test (as per Section 11 of this directive), or
- The test is found to produce invalid results identified by users, or through some other program.

11. MANUFACTURER NOTIFICATION RESPONSIBILITIES

Manufacturers of rapid tests that have received a GIPSA Certificate of Performance must notify the Test Kit Program Manager in writing when any changes or alterations are made to the rapid test, including changes in chemical reagents, equipment, or procedures. Failure to notify GIPSA of these changes will serve as grounds for immediate withdrawal of the GIPSA Certificate of Performance. The Test Kit Program Manager will determine the significance of any changes and advise the manufacturer if it will be necessary to prepare another data submission.

12. CONTACT INFORMATION

Direct any correspondence regarding this Program to the GIPSA Test Kit Program Manager:

- E-mail: Tim.D.Norden@usda.gov
- Mail Address:

  Test Kit Program Manager
  USDA, GIPSA, TSD
  10383 North Ambassador Drive
  Kansas City, MO 64153-1394

/s/

Steven N. Tanner, Director
Technical Services Division